



CANNON BUILDING
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STATE OF DELAWARE
OFFICE OF CONTROLLED SUBSTANCES

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PUBLIC MEETING NOTICE:	CONTROLLED SUBSTANCE COMMITTEE
DATE AND TIME:	Wednesday May 23, 2018 at 9:00 a.m.
PLACE:	Buena Vista Conference Center, 2nd Floor, 661 S. DuPont Highway, New Castle, Delaware 19720
APPROVED:	

MEMBERS PRESENT

Joseph Parise, DO, Medical Representative
Jo Ann M. Baker, DNP, RN, FNP-C, Nursing Representative
Danielle Downs, DVM, Veterinary Representative
Alex Zarow, R.Ph., Pharmacy Representative
Linda H. Ciavarelli, DPM, Podiatric Representative
Mark Hanna, Public Representative
Kirsten Opalach, PA-C, PA Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative

MEMBERS ABSENT

Michael Kremer, DMD, Dental Representative, President
Jason Slavoski, PharmD, Pharmacist Administrator (PMP)

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David Mangler, Director, Division of Professional Regulations
Geoff Christ, Executive Director Office Controlled Substance, Drug Administrator
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, R.Ph., Pharmacist Compliance Officer

ALSO PRESENT

Hooshang Shanehsaz
Tejal Patel
Jeanne Chiquoine
Deb Hamilton

CALL TO ORDER

Mr. Von Goerres called the meeting to order at 9:05 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Mr. Zarow, seconded by Dr. Parise, to approve the minutes for March 28, 2018. The motion unanimously carried.

UNFINISHED BUSINESS

Deliberations – Proposed Rules and Regulations Changes

A motion was made by Ms. Downs and seconded by Dr. Parise, to approve proposed rules and regulations changes.

PRESIDENT'S REPORT

No Report

NEW BUSINESS

DIRECTOR'S REPORT

Case/Diversion Review

No Report

Current Events

Mr. Christ attended an informal Medical Society meeting for potential stakeholders in regards to mandating ePrescribing. He informed that Veterinarians would be exempted from ePrescribing.

Mr. Christ also attended NABP meeting in Denver which passed resolutions for ePrescribing.

He reported that the Division is working on a contract with AB&C Media Co. for an educational CE course for mandatory CE.

Dr. Parise expressed concerns in regards to electronic medical records not working appropriately. Mr. Christ informed that if ePrescribing software malfunctioned, one would still be able to manually write a script.

He reported that about 70% of regular prescriptions are ePrescribed, but the number drops significantly when it comes to Controlled Substances.

Mr. Christ noted that he attended a Safe Prescribing subcommittee meeting. The meetings focus was centered on opioid practitioner education, and informed consent forms and their design.

He informed that two bills are going through Legislature, one is an opioid tax and one is an impact fee. The opioid tax is on the sale of opioids, and the impact fee correlates to the number of MMEs per dispensed container.

HB331 – pertains to Benzodiazepine prescribing, and the physician's requirement to document the patient's chart before prescribing. If the patient is under 18, they need parental consent. The Department of Health is writing an informational pamphlet for patients that can be given by the Pharmacist when Benzodiazepines are prescribed.

HB401 – removes any cannabinoid drugs that were FDA approved from Schedule I.

Prescription Monitoring Program (PMP) Review – Jason Slavoski

Mr. Christ reported (since Mr. Slavoski was out of town for a CDC meeting) that PMP is now connected to 19 states as they just added Massachusetts, Rhode Island, and D.C. PMP is still working on integrating electronic health records with pharmacy dispensing systems. As of now, about 50 pharmacies in DE will have PMP as a single sign on, and by the end of August, all 5 health systems with exception of DuPont will be able to access PMP single sign on through the electronic health records. APPRISS has produced 5 different educational PMP videos.

He reported that PMP is working diligently on validation of licensee's versus PMP registration and is now down to less than 2000 as opposed to the initial 4500 people that had not yet logged in but had registered accounts. Dr. Parise inquired as to when disciplinary actions will be taken for noncompliant registrations. Mr. Mangler expressed that it is necessary that validation of licensee's be completed to ensure appropriate disciplinary action is taken.

There is a Mega Bill in Senate that will combine data from other agencies (such as Public Health, Office of Emergency Management, substance abuse, mental health, etc.) into PMP in effort to assist with the opioid epidemic and intervene as necessary. Mr. Mangler stated there is certain language in the bill that when able requires importation of EMS data, such as suspected field overdoses, into the PMP which creates a prescription record. For example, the prescriber could see if a person had a suspected overdose several weeks prior before prescribing a medication. Mr. Mangler also stated that Federal agencies will be required to use and report to their state's PMP. Mr. Christ reported a proposed federal regulation up for comment until June 25th, and will require DA and Federal systems to report to their respective state's PMP.

PROPOSED REGULATION CHANGES

Review of Regulation 4.1.2 and 4.1.3

Mr. Christ reported that regulation 4.1.2 makes an exception for hospice patients that the prescriber could communicate a controlled substance to the pharmacy. However, 4.1.3 says that all verbal prescriptions must be verified and authorized by their prescriber which is contradictory. Ms. Kelly proposed to add "except hospice and long-term care" to 4.1.3.

Partial Filling of Schedule II Controlled Substances

Mr. Christ stated that in July 2016, the Comprehensive Addiction and Recovery Act was signed by O'bama which put into Federal Code that pharmacist could partially fill a CSII. Mr. Christ proposed a change in regulation to offer partial fill to patients other than long-term care and hospice, but with 30 days or void. This could reduce unused medications quantities, and potential abuse.

Mr. Zarow was concerned about issues arising from insurance copays. Mr. Christ will look into copays regarding partial pay and additional costs.

A motion was made by Ms. Downs and seconded by Dr. Parise, to approve the proposed regulation change for review at the next meeting.

COMMITTEE REPORTS

Medical Examiner's Report

No Report

DEA Report

No report

Substance Abuse Report

No Report

Law Enforcement Report

No Report

Regulatory Committee Report

No Report

Legislative Committee Report

No Report

INSPECTION REPORT

Ms. McCreary provided the following report:

1 – Opening - Pill Box Pharmacy, Millsboro, De. – had to transfer all drugs out and then back in and are operating under a different name and new ownership, and just regained DEA and CSR registration.

Continuing Education Review

Aniqua Alam – submitted additional information and course catalogs (with syllabus) in regards to the continuing education audit. A motion was made by Ms. Downs and seconded by Dr. Parise, to approve the audit.

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

Ms. Opalach stated that recently an oncology patient was self-treating end-stage cancer pain with medication ordered online that was received from India. They were not sure whether to start the patient on Opioids as they did not know exactly what they were receiving from the shipments from India used as pain management.

Ms. Downs stated that there is a shortage of working dogs in the US.

PUBLIC COMMENT

NEXT SCHEDULED MEETING

The next regular meeting will be held on July 25th, 2018 at 9:00 am at the Buena Vista Conference Center, 2nd Floor, DuPont Room.

ADJOURNMENT

A motion was made by Dr. Parise, seconded by Ms. Downs, to adjourn the meeting at 10:09 am. The motion carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'J. Mason', followed by a horizontal line.

Jessica Mason
Administrative Specialist III
Office of Controlled Substances